

K 962402  
510(k) Summary  
AMO® Prestige® Day Pack

SEP 19 1996

1. **Submitter's name, address, telephone number, a contact person, and the date the summary was prepared:**
  - a. Allergan, Inc.  
2525 Dupont Drive  
Irvine, California 92715  
(714) 246-2226
  - b. Contact Person: Monique M. Heyninck
  - c. Date Summary Prepared: June 20, 1996
2. **Name of device, including trade name and classification name:**
  - a. Name of Device: AMO® Prestige® Day Pack
  - b. Common Name: Phacofragmentation or I/A Tubing Pack
  - c. Classification Name: As per 21 CFR 886.4670, the product nomenclature is Phacofragmentation System.
3. **Identification of the predicate for legally marketed device or devices to which substantial equivalence is being claimed:**
  - a. I/A disposable tubing system for use with the AMO® Prestige® phacoemulsification machine:  
  
AMO® Prestige® Pack (Disposable, Sterile), OPO-40
  - b. I/A tubing system for use with the AMO® Diplomax™ phacoemulsification machine:  
  
AMO® One Bottle Reusable Tubing (Sterile)  
AMO® One Bottle Disposable Tubing (Sterile)  
AMO® Irrigation Administration Set (Sterile)  
AMO® T-Fitting (Non-Sterile)

4. A description of the device that is the subject of the 510(k), including an explanation of how the device functions, basic scientific concepts, significant physical and performance characteristics (design, material, physical properties).

The AMO® Prestige® Day Pack has been designed for single patient use or multiple reuse and is used with the AMO® Prestige® Advanced Cataract Extraction™ System. The Day Pack is comprised of the AMO® Prestige® Disposable Cartridge Assembly, the AMO® Prestige® Disposable I/A Tubing Assembly and the AMO® Prestige® Drip Spike Assembly, all of which are provided to the customer in a sterile configuration. The AMO® Prestige® Day Pack provides a conduit for the irrigation fluid used to replenish the intraocular fluid removed during cataract extraction. The tubing pack also provides a conduit for the aspiration fluid that contains the aspirated fluid and nuclear fragments removed during cataract surgery. The design, materials and physical properties of the AMO® Prestige® Day Pack are substantially equivalent to those used in the predicate devices.

5. Statement of intended use:

The AMO® Prestige® Day Pack supports the irrigation fluid path for replenishing intraocular fluid removed during cataract extraction. The tubing pack also supports the aspiration fluid path for removing fluid and nuclear fragments during cataract surgery.

6. Statement of how the technological characteristics (i.e. design, materials, chemical composition, energy source) compare to the predicate device:

	AMO® Prestige® Day Pack	Predicate Devices*
Intended Use	The Day Pack supports the irrigation and aspiration fluid paths during the phacoemulsification procedure.	The Predicate Devices support the irrigation and aspiration fluid paths during the phacoemulsification procedure.
Tubing Material	Kynar, Polypropylene and Silicone	Kynar, Polypropylene, Silicone, and PVC
Sterilization Method	Gamma Radiation and EtO	Gamma Radiation and EtO
Reusable Cartridge	No	Yes/No
Reusable Tubing	Yes	Yes/No
Disposable Tubing	Yes	Yes
Reusable Drip Spike Assembly	No	Yes/No
Reusable Drain Bag	Yes	Yes/No

\* AMO® Prestige® Pack, OPO-40, and the tubing sets and accessories of the AMO® Diplomax™.

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**7. Brief summary of nonclinical tests and results:**

The performance testing conducted on the AMO® Prestige® Day Pack included the following:

- Durability Tests
- Worst Case Sterilization
- Aspiration Obstruction
- Chamber Maintenance

The results of these tests indicate that the AMO® Prestige® Day Pack is substantially equivalent to the currently marketed predicate devices and is compatible for use with the AMO® Prestige® Advanced Cataract Extraction™ System.